



Attorney Docket No. 2422-X9

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

CHERUKURI

Examiner: B. Fubara

Serial No.: 09/982,093

Art Unit: 1615

Filed: October 19, 2001

For: DRUG DELIVERY SYSTEMS

TRANSMITTAL LETTER

Commissioner for Patents
Washington, D.C. 20231

Sir:

Submitted herewith for filing in the U.S. Patent and
Trademark Office is the following:

- 1) Transmittal Letter; and
- 2) Response to Restriction Requirement.

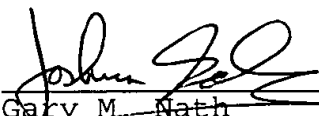
The Commissioner is specifically authorized to charge any
required fee deficiency under 37 CFR §§ 1.16 or 1.17, or credit
any overpayment, to Deposit Account No. 14-0112 in connection
with this matter.

Respectfully submitted,

NATH & ASSOCIATES PLLC

Date: August 7, 2002
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Attorney Docket No. 24222-X3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

CHERUKURI

Examiner: B. Fugere

Serial No.: 09/982,093

Art Unit: 1615

Filed: October 19, 2001

For: DRUG DELIVERY SYSTEMS

RESPONSE TO RESTRICTION/ELECTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in response to the Official Action dated July 8, 2002. The one-month shortened statutory period for response is set to expire August 8, 2002. Accordingly, this Response is filed within the period for reply set by the Examiner.

SUMMARY OF ELECTION REQUIREMENT

The Examiner has required applicants to elect a single disclosed species encompassed by claims 1-24 for prosecution on the merits as follows:

This application contains claims directed to the following patentably distinct species of the claimed invention: Various encapsulated products.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, an encapsulated product comprising a therapeutic agent, at least on compressible material and at least one lubricating material is generic.

Applicant must elect one of the following pharmaceutical agents for the encapsulated product:

(a) A psychotropic agent recited in claims 3-8

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- (b) A gastrointestinal agent recited in claims 9-18
- (c) A migraine therapeutic agent recited in claims 19-21
- (d) A hypertension therapeutic agent recited in claims 22-24

If applicant elects any of groups (a) through (d), applicant must further elect a specific pharmaceutical agent that is embodied in the elected group. For example, if applicant elects (a) above, applicant must elect a specific psychotropic agent that is recited in the claims. See claims 4-8 psychotropic agents.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention **(a specific pharmaceutical for the encapsulated product)** to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Gary M. Nath (Leanne Kibler) on 07/03/02 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or

more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

ELECTION

Applicants provisionally elect the pharmaceutical agent for the encapsulated product of Group (a), a psychotropic agent recited in claims 3-8, with traverse. Applicants further provisionally elect Venlafaxine as the specific pharmaceutical agent of this elected group as required by the Examiner. Claims 1-8 are readable upon the election made herein.

TRAVERSAL

Applicants respectfully traverse the Examiner's restriction requirement for the following reasons.

The election requirement is improper because it omits "an appropriate explanation" as to the existence of a "serious burden" if an election were not required. (MPEP § 803). An examination of all the claims in this application would not pose a serious burden because a search for an encapsulated product containing any one of the particular groups of therapeutic agents noted by the Examiner would require searching the prior art areas appropriate to encapsulated products containing the other groups of therapeutic agents noted by the Examiner.

Moreover, these classes of therapeutic agents are all assigned to the Examiner's art unit. Given their overlapping subject matter and identical classifications, examinations of all the therapeutic agents would not pose a serious burden because they would be coextensive.

Additionally, applicants have paid a filing fee for an examination of all the claims in this application. If the Examiner refuses to examine the claims paid for when this application was filed, applicants must pay duplicative fees to file a divisional application for the non-elected or withdrawn groups of claims.

CONCLUSION

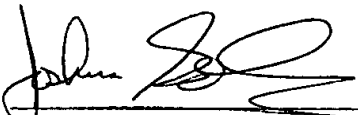
In view of the foregoing, applicants respectfully request the Examiner to reconsider and withdraw the restriction requirement and to examine claims 1-24 pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Date:

August 7, 2002
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Respectfully submitted,
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